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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,532	03/20/2001	David Allen Schul	8003	2563

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/23/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/812,532

SCHUL ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003 and 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 10, 2003 has been entered in Paper No. 14.

This Office Action is a response to Applicant's request for continued examination (RCE) filed February 10, 2003 in Paper No. 14, and amendment and response to the Final Office Action (mailed October 1, 2002), filed February 10, 2003 in Paper No. 15 wherein claims 1-41 and 51-56 are cancelled, and claims 57-68 are newly submitted. Applicant's supplemental amendment filed April 14, 2003, wherein the instant claims 57-68 have been amended to clearly define that the instant sterol ester composition is a sterol fatty acid ester composition as suggested by the examiner in the telephone call (April 14, 2003), has been entered in Paper No. 16.

Currently, claims 57-68 are pending in this application.

Claims 57-68 are examined on the merits herein.

The provisional application 60/192,412 upon which priority is claimed, appears to provide adequate support for the instant application, i.e., claims 57-68.

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Applicant's amendment filed on February 10, 2003 in Paper No. 15 with respect to the rejection of claims 51-56 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "a free sterol level of less than 10%" of record in the Office Action dated October 1, 2002 have been fully considered and found persuasive to remove the rejection since claims 51-56 have been cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Erickson (3,751,569, PTO-1449 submitted February 11, 2002).

Erickson discloses a clear cooking and salad oil comprising 0.5-10% by weight of the composition of a sterol fatty acid ester, which comprises 100% the particular monounsaturated fatty acid moiety, oleic acid moiety (oleic acid is a known monounsaturated fatty acid, see its chemical structure provided in the Merck Index page 6967). The sterol fatty acid ester employed in the composition therein is β -sitosteryl oleate or stigmasteryl oleate (see particularly Table I at col. 3-4 and Table II at col.5). See also col.1 lines 14-18 and 59-65; col.3 lines 1-30. Thus, the sterol oleic acid esters, β -sitosteryl oleate or stigmasteryl oleate, in the composition therein comprise about

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100% oleic acid moiety, which reads on more than 50% monounsaturated fatty acid moiety recited in the claim 57.

Thus, Erickson anticipates claim 57.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (5,502,045, of record) and Wester et al. (WO 99/56558, of record).

Miettinen et al. disclose that sterol fatty acid esters such as fatty acid esters of β -sitosterol and β -sitostanol are useful in compositions for reducing serum cholesterol level. See abstract, col.1 lines 10-15, col.3 lines 45-50, col.4 lines 19-24 and 64-65. The sterol fatty acid ester compositions therein can be added to oils (see particularly in Example 2-4 at col.5-6), such as at 3, 6, and 13 % by weight to rapeseed oil (Example 2-3 at col.5-6), and at about 10-20% weight to margarine (see Example 2-5 at col.5-6), and especially the rapeseed oil with the ester mixture added remained clear at room temperature (known at about 60-70°F) (see col.6 lines 23-25). Miettinen et al. also disclose that the sterol fatty acid esters therein employed in the compositions are prepared by, for example, β -sitostanol and rapeseed oil fatty acid methyl ester (i.e.,

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interesterifying rapeseed oil fatty acid methyl ester with β -sitostanol to make β -sitostanol rapeseed oil fatty acid esters, see particularly at Example 1 at col.5 lines 34-47). The conversion rate of esterification therein was achieved to 98% (see col.5 lines 45-46). Thus, one of ordinary skill in the art would clearly recognize that the unesterified sterol level therein could be 2%, within the instant claim, less than 3, 5, or 10%.

Wester et al. discloses that fatty acid esters of phytosterols and phytostanols (such as sitosterol, campesterol and stigmasterol) are known to be useful in compositions for reducing serum cholesterol level. See abstract, page 1-3. Wester et al. also disclose that these sterol fatty acid esters compositions can be added to cooking oils and salad oils for the same purpose to reduce serum cholesterol level. See page 4 lines 9-31. Wester et al. also disclose that rapeseed oil employed for making stanol fatty acid esters is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (mainly monounsaturated) (see particularly at page 5 lines 14-17). Wester et al. further disclose that particular sterol fatty acid esters compositions comprise less than 5 or 7% saturated fatty acids (SFAs) (see particularly page 5 lines 8-9, and claims 1-2) and more than 50% PUFA as fatty acid moieties (see particularly page 5 lines 6-7 and claims 1-7).

Miettinen et al. and Wester et al. do not expressly disclose particular sterol fatty acid esters compositions herein comprising more than 50%, about 55-80%, or about 60-70% of fatty acid moieties which are monounsaturated fatty acids (MUFAs) and less 50% polyunsaturated fatty acids (PUFA) moieties.

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less 50% PUFA moieties in particular sterol fatty acid esters compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less 50% PUFA moieties in particular sterol fatty acid esters compositions herein since the sterol rapeseed oil fatty acid esters compositions at about 10% by weight are known to be added into the edible oil according to Miettinen et al. Moreover, rapeseed oil is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (including monounsaturated fatty acids and polyunsaturated fatty acids) but mainly monounsaturated fatty acids according to Wester et al. Thus, one of ordinary skill in the art would have reasonably interpreted that mainly monounsaturated fatty acids in a high content of unsaturated fatty acids, might be more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids in rapeseed oil. Hence, based on the teachings of Wester et al., the sterol rapeseed oil fatty acid esters compositions of Miettinen et al. would have reasonably been considered to comprise more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids.

Moreover, both Miettinen et al. and Wester et al. teach the same therapeutic usefulness of sterol fatty acid ester compositions for reducing serum cholesterol level

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and these sterol fatty acid esters compositions can be added to cooking oils and/or salads oils for the same therapeutic purpose. Therefore, one of ordinary skill in the art would have found it obvious to employ sterol rapeseed oil fatty acid esters compositions comprising more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid moieties and less than 50% PUFA moieties in an edible oil.

Therefore, the combined teachings of Miettinen et al. and Wester et al. have clearly provided the motivation of the instant claimed sterol fatty acid ester compositions.

Further, the optimization of known amounts of active agents, e.g., monounsaturated fatty acids, polyunsaturated fatty acids, and saturated fatty acids in a known composition to achieve desirable physical properties is considered well within the skill of artisan, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on February 10, 2003 in Paper No. 15 with respect to the rejection of claims 1-41 and 51-56 made under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (5,502,045) and Wester et al. (WO 99/56558) in view of Letton et al. (5,306,516) and Dickson et al. (5,869,304) for reasons of record stated in

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the Office Action dated October 1, 2002 have been fully considered but are moot since claims 1-41 and 51-56 have been cancelled, and the new ground(s) of rejection for the newly submitted claims set forth above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 17, 2003